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10/081,554	02/22/2002	Hiroto Yoshii	B588-027	4281

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EXAMINER	
MAHATAN, CHANNING	
ART UNIT	**PAPER NUMBER**
1631	

DATE MAILED: 02/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/081,554	YOSHII, HIROTO	
	Examiner	Art Unit	
	Channing S Mahatan	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 November 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11 and 13-50* is/are pending in the application.

4a) Of the above claim(s) *22-45,49 and 50* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11,13-21 and 46-48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-11 and 13-50* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

APPLICANTS' ARGUMENTS

Applicants' arguments, filed 26 November 2004, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

CLAIMS UNDER EXAMINATION

Claims herein under examination are claims 1-11, 13-21, and 46-48. Claim 12 has been canceled. Claims 22-45, 49, and 50 remain withdrawn as directed to a non-elected invention.

Claims Rejected Under 35 U.S.C. § 101

35 U.S.C. § 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-11, 13-21, and 46-48 are rejected under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter.

NON-STATUTORY SUBJECT MATTER

Claims 1-11, 13-21, and 46-48 are rejected under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter. The instant claims are directed to a method, information processing apparatus, program, and storage medium comprising steps for the determination of a probe candidate by the steps of "generation", "extraction", "evaluation", and "determination" without any physical alteration step, which is considered to be non-statutory subject matter. Applicants are directed to the following section of the M.P.E.P. for guidance of

this rejection.

M.P.E.P. Section IV. DETERMINE WHETHER THE CLAIMED INVENTION COMPLIES WITH 35 U.S.C. 101, B. Classify the Claimed Invention as to Its Proper Statutory Category, 1. Nonstatutory Subject Matter, (b) Nonfunctional Descriptive Material states:

Descriptive material that cannot exhibit any functional interrelationship with the way in which computing processes are performed does not constitute a statutory process, machine, manufacture or composition of matter and should be rejected under 35 U.S.C. 101. Thus, Office personnel should consider the claimed invention as a whole to determine whether the necessary functional interrelationship is provided. Where certain types of descriptive material, such as music, literature, art, photographs and mere arrangements or compilations of facts or data, are merely stored so as to be read or outputted by a computer without creating any functional interrelationship, either as part of the stored data or as part of the computing processes performed by the computer, then such descriptive material alone does not impart functionality either to the data as so structured, or to the computer. Such "descriptive material" is not a process, machine, manufacture or composition of matter. (Data consists of facts, which become information when they are seen in context and convey meaning to people. Computers process data without any understanding of what that data represents. Computer Dictionary 210 (Microsoft Press, 2d ed. 1994).)
The policy that precludes the patenting of nonfunctional descriptive material would be easily frustrated if the same descriptive material could be patented when claimed as an article of manufacture. For example, music is commonly sold to consumers in the format of a compact disc. In such cases, the known compact disc acts as nothing more than a carrier for nonfunctional descriptive material. The purely nonfunctional descriptive material cannot alone provide the practical application for the manufacture. Office personnel should be prudent in applying the foregoing guidance. Nonfunctional descriptive material may be claimed in combination with other functional descriptive multi-media material on a computer-readable medium to provide the necessary functional and structural interrelationship to satisfy the requirements of 35 U.S.C. 101. The presence of the claimed nonfunctional descriptive material is not necessarily determinative of nonstatutory subject matter. For example, a computer that recognizes a particular grouping of musical notes read from memory and upon recognizing that particular sequence, causes another defined series of notes to be played, defines a functional interrelationship among that data and the computing processes performed when utilizing that data, and as such is statutory because it implements a statutory process.

M.P.E.P. section entitled "Statutory Process Claims" (page 2100-15, Column 1-2) states:

A claim that requires one or more acts to be performed defines a process. However, not all processes are statutory under 35 U.S.C. 101. Schrader, 22 F.3d at 296, 30 U.S.P.Q.2d at 1460. To be statutory, a claimed computer-related process must either: (A) result in a physical transformation outside the computer for which a practical application in the technological arts is either disclosed in the specification or would have been known to a skilled artisan (discussed in i) below), or (B) be limited to a practical application within the technological arts (discussed in ii) below). See Diamond v. Diehr, 450 U.S. at 183-84, 209 U.S.P.Q. at 6 (quoting Cochrane v. Deener, 94 U.S. 780, 787-88 (1877)) ("A [statutory] process is a mode of treatment of certain materials to produce a given result. It is an act, or a series of acts, performed upon the subject-matter to be transformed and reduced to a different state or thing.... The process requires that certain things should be done with certain substances, and in a certain order; but the tools to be used in doing this may be of secondary consequence."). See also Alappat, 33 F.3d at 1543, 31

> U.S.P.Q.2d at 1556-57 (quoting Diamond v. Diehr, 450 U.S. at 192, 209 U.S.P.Q. at 10). See also id. at 1569, 31 U.S.P.Q.2d at 1578-79 (Newman, J., concurring) ("unpatentability of the principle does not defeat patentability of its practical applications") (citing O 'Reilly v. Morse, 56 U.S. (15 How.) at 114-19). If a physical transformation occurs outside the computer, a disclosure that permits a skilled artisan to practice the claimed invention, i.e., to put it to a practical use, is sufficient. On the other hand, it is necessary for the claimed invention taken as a whole to produce a practical application if there is only a transformation of signals or data inside a computer or if a process merely manipulates concepts or converts one set of numbers into another.

M.P.E.P. 2106 (IV)(B)(2)(b), part ii) states:

> "For example, a computer process that simply calculates a mathematical algorithm that models noise is nonstatutory. However, a claimed process for digitally filtering noise employing the mathematical algorithm is statutory."

Similar to the non-statutory example above, the instant invention comprises algorithmic steps for analyzing and modeling data directed to amino acid sequence without any physical alteration resulted from said analysis or modeling steps. It is acknowledged that the instant invention comprises steps for generating a tree of "a plurality of partial base sequences" (data) obtained on the basis of "a plurality of target base sequences" (data) and analyzes (i.e. modeling) the "plurality of partial base sequences" to be used as probe, however as stated in the M.P.E.P. 2106 (IV)(B)(2)(b), part ii):

> "such activity is not determinative of whether the process is statutory because such transformation alone does not distinguish a statutory computer process from a nonstatutory computer process.

Therefore, the instant claims do not recite any concrete or tangible results; therefore the claims do not recite statutory subject matter.

Claims Rejected Under 35 U.S.C. § 112 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-11, 13-21, and 46 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

VAGUE AND INDEFINITE

Claims 1 and all claims dependent therefrom are indefinite due to the recitation of a preamble that is different from the actual claimed method steps. The preamble states that it is "A method of determining a probe candidate that is utilized for designing a base sequence to be used as a probe which is hybridized with an unknown nucleic acid fragment to perform analysis", however, the claim recites several steps with a final step of "a determination step of determining a partial base sequence to be used as a probe on the basis of the evaluation result in the evaluation step". There is no indication in the body of the instant claim that "a probe candidate that is utilized for designing a base sequence to be used as a probe which is hybridized with an unknown nucleic acid fragment to perform analysis" is intended to be determined as recited in the preamble. Therefore, because of the differences between the preamble and actual method steps it is unclear whether the preamble or the method steps set forth in the claims after the preamble control the metes and bounds of the claims. Clarification of the metes and bounds of the claim is requested, via clearer claim wording.

Claim 7 recites the further limitation of the evaluation step to comprise "introducing an evaluation function which multiples a change in entropy by a weight which reduces a distance from the center of a partial base sequence corresponding to the desired node increases" is considered vague and indefinite. From the instant claim language it appears that the evaluation function is to multiple "a change in entropy by a weight" wherein said weight "reduces a

distance from the center of a partial base sequence" that corresponds "to the desired node increases". Further, absent from claims 1 & 6 are the identified "desired node increases" as recited in instant claim 7. Clarification of the metes and bounds of the claim is requested, via clearer claim wording.

Claims 46 recites "An information processing apparatus" which is understood to be a machine device, however, absent from the instant claims are any parts/modules/hardware of the said device. For instance, if it is Applicants' intent that the "information processing apparatus" is similar to a computer the instant claims fail to denote memory, processor, display, etc. (i.e. hardware) "for performing the method of determining a probe candidate according to claim 1". Clarification of the metes and bounds, via clearer claim language, is requested.

Claims Rejected Under 35 U.S.C. § 102

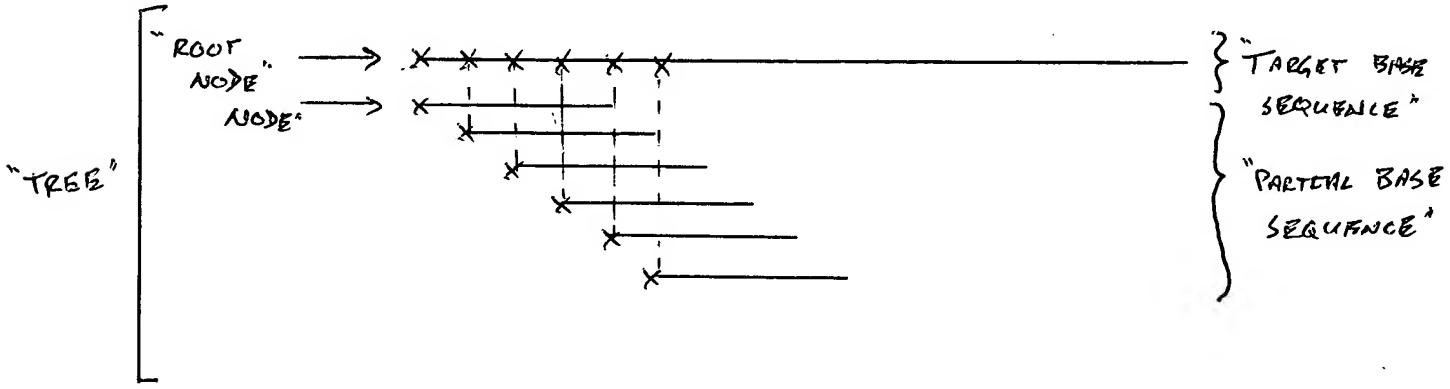
The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 14, 15, 18-21, and 46 are rejected under 35 U.S.C. § 102 (b) as being anticipated by Shannon et al.

Shannon et al. discloses a method for predicting the potential of an oligonucleotide to hybridize to a target nucleotide sequence (Abstract). The following describes the depiction in Figure 2 and the corresponding description in the specification of Shannon et al. is noted.
First, a sequence ("target base sequence") is utilized to generate candidate probes ("partial base sequence") of every possible starting position (instant claims 1, 3, and 4 "generation step" and

claim 2; Columns 6-7, lines 66-67 and 1-5, respectively; and Column 7, lines 19-23). An example of this generation of candidate probes is depicted (Columns 29-34) wherein the start position of each candidate probe is the "node" (the terminating point of two or more lines; refer to below definition) and the "root node" is located on the target base sequence (i.e. tree). To clarify this point the Examiner has provided the following illustration:



Second, parameters of each of these candidate probes (partial base sequences) is determined (instant claim 1 "extraction step"; Column 7, lines 5-16). Third, candidate probes that satisfy (i.e. cut-off values) a particular set of parameters ("calculated specificity"; i.e. melting temperature, etc.) are evaluated/filtered (instant claim 1 "evaluation step"; Column 7, lines 16-19). Finally, candidate probes are selected as probes based upon the evaluation (instant claim 1 "determination step"; Column 26, lines 13-36). The inventors list particular parameters/thermodynamic factors (i.e. oligonucleotide size/length, melting temperature, entropy, etc.) to be applied in the steps of oligonucleotide evaluation and determination as probes for the target sequence (instant claims 18-21; Column 7, lines 5-19; Columns 13-14, lines 48-67 and 1-9, respectively; and Table 1). Oligonucleotides in the subset are clustered (grouped) along a region of the nucleotide sequence that is hybridizable to the target nucleotide (instant claims

10, 11, 14, & 15; Column 7, lines 19-27; and Column 26, lines 13-36). The disclosed method is indicated as being operated in a computer (instant claim 46 "information processing apparatus"; Columns 7-8, lines 47-67 and 1-8, respectively; and Column 28, lines 21-27). Thus, Shannon et al. anticipates the instantly claimed invention.

It is noted the term "node", as applied by the Examiner in the above 35 U.S.C. § 102(b) rejection, is understood be defined as follows:

> "node...5. The intersection or terminating point of two or more lines or curves." (Webster's II New Riverside University Dictionary. Houghton Mifflin Company. 1984, page 797)

Claims 47 and 48 are rejected under 35 U.S.C. § 102 (b) as being anticipated by Boebert et al. (U.S. Patent Number 4,621,321).

Boebert et al. discloses a system and program that provides access to system files (Abstract), therefore allowing the computer to access and execute a system file (i.e. method of determining a probe candidate") (claim 47; Column 1, lines 21-35). Borbert et al. indicate that such computer program is stored on "storage medium" (claim 48; Column 12, lines 36-68). Thus, Borbet et al. anticipates the instantly claimed invention.

EXAMINER INFORMATION

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 C.F.R. § 1.6(d)). The CM1 Fax Center number is either 571-273-8300.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Channing S. Mahatan whose telephone number is (571) 272-0717. The Examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D., can be reached on (571) 272-0718.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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Examiner Initials: CSM

Date: February 5, 2005

Ardin H. Marschel 2/6/05
ARDIN H. MARSCHEL
PRIMARY EXAMINER